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### UNITED STATES PATENT AND TRADEMARK OFFICE

### BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte QINGHONG LI

Appeal 2015-001702 Application 13/505,912 Technology Center 1600

Before DONALD E. ADAMS, MELANIE L. McCOLLUM, and TAWEN CHANG, *Administrative Patent Judges*.

ADAMS, Administrative Patent Judge.

### DECISION ON APPEAL<sup>1</sup>

This appeal under 35 U.S.C. § 134(a) involves claims 15–20 (App. Br.<sup>2</sup> 5). Examiner entered rejections under 35 U.S.C. § 101 and 35 U.S.C. § 102(b). We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

### STATEMENT OF THE CASE

Appellant discloses "a set of biomarkers of aging in the heart, comprising several genes involved in the Wnt signaling pathway" and "the

<sup>&</sup>lt;sup>1</sup> Appellant identifies "[t]he real party in interest [as] Nestec, S.A." (App. Br. 3).

<sup>&</sup>lt;sup>2</sup> All reference to Appellant's Brief, relates to the Appeal Brief received July 22, 2014.

use of those biomarkers to identify nutrients and dietary regimens for retarding heart aging, and for modulation of the genes themselves to retard heart aging" (Spec. ¶ 2). Claim 15 is representative and reproduced below:

- 15. A method for screening an agent or regimen for the ability to retard heart aging comprising the steps of:
  - (a) determining a first gene expression profile by:
    - (i) isolating nucleic acids from a heart tissue sample from an untreated aged subject;
    - measuring transcription or translation (ii) products of hybridizing the nucleic acids from the sample with a plurality of probes capable of specifically hybridizing to one or more polynucleotide molecules to form one or more hybridization complexes, wherein the probes are each at least 10 nucleotides in length and wherein the probes are identical to or are sufficiently complementary to a corresponding region of the polynucleotide molecules to which they specifically hybridize and the corresponding region distinguishes each polynucleotide molecule from any other polynucleotide molecule in the sample, and wherein the polynucleotide molecules comprise Ctnnb 1 and optionally one or more genes related to Wnt signaling in heart tissue from an aged subject in the absence of the agent or regimen; and
    - (iii) detecting the hybridization complexes;
  - (b) determining a second gene expression profile by:
    - (i) administering the agent or regimen to a treated aged subject;
    - (ii) isolating nucleic acids from a heart tissue sample from said treated aged subject;
    - (iii) measuring transcription or translation products of hybridizing the nucleic acids from the sample with a plurality of probes capable of specifically hybridizing to one or

more polynucleotide molecules to form one or more hybridization complexes, wherein the probes are each at least 10 nucleotides in length and wherein the probes are identical to or are sufficiently complementary to a corresponding region of the polynucleotide molecules to which they specifically hybridize and the corresponding region distinguishes each polynucleotide molecule from any other polynucleotide molecule in the sample, and wherein the polynucleotide molecules comprise Ctnnb 1 and optionally one or more genes related to Wnt signaling in heart tissue from an aged subject in the presence of the agent or regimen; and

(iv) detecting the hybridization complexes;
(c) comparing the first gene expression profile with the second gene expression profile, wherein a change in the second gene expression profile of at least 1.2 fold indicates that the agent material or regimen is likely to be useful in retarding heart aging when administered to an individual.

The claims stand rejected as follows:

Claims 15–20 stand rejected under 35 U.S.C. § 102(b) as anticipated by Barger.<sup>3</sup>

Claims 15–20 stand rejected under 35 U.S.C. § 101 as directed to non-statutory subject matter.

<sup>&</sup>lt;sup>3</sup> Barger et al., A Low Dose of Dietary Resveratrol Partially Mimics Caloric Restriction and Retards Aging Parameters in Mice, 3 PLoS One e2264–e2265 (2008).

Anticipation:

### **ISSUE**

Does the preponderance of evidence on this record support Examiner's finding that Barger teaches Appellant's claimed invention?

### **ANALYSIS**

Examiner finds that Barger anticipates Appellant's claimed invention (Ans. 4–6). We adopt Examiner's findings concerning the scope and content of the prior art (*id.*).

Examiner finds, *inter alia*, that Barger "teach[es] the Affymetrix Mouse Genome 430 2.0 array. This array comprises probes for a plurality of polynucleotides including Ctnnb1, as disclosed by [Appellant's] Specification which describes using said array to identify Ctnnb1" (Ans. 8, citing Appellant's Specification at ¶ 106–111; *see* App. Br. 18). Therefore, Examiner finds that Barger teaches "a plurality of probes capable of specifically hybridizing to one or more polynucleotide molecules [. . .] wherein the polynucleotide molecules comprise Ctnnb1" (Ans. 8). For the foregoing reasons, we are not persuaded by Appellant's contention that Barger does not disclose "polynucleotide molecules [that] comprise Ctnnb1" (App. Br. 17).

We agree with Examiner's rationale and finding that Appellant's "claim 15 does not [require] that the first gene expression profile is 'based on Ctnnb1' or that a change in the second gene expression profile is 'based on genes related to Wnt signaling'" (Ans. 8–9). Therefore, we are not persuaded by Appellant's contention that "Barger does not compare the first gene expression profile with the second gene expression profile based on Ctnnb1 or any other genes related to Wnt signaling in heart tissue" or "based

on genes related to Wnt signaling in heart tissue (Ctnnb1 or any other Wnt signaling gene)" (App. Br. 17; see Reply Br. 8).

Appellant recognizes that "Barger discloses the use of resveratrol and calorie restricted diet to inhibit gene expression profile associated with cardiac and skeletal aging" (App. Br. 17). In this regard, Examiner finds that Barger teaches that "resveratrol supplementation at low doses is likely a robust intervention in the retardation of cardiac aging; e.g. p. 2, 1st column, 3rd paragraph; and e.g. p.3, Fig 1A, showing the comparison of resveratrol and age on gene expression, with significant changes in gene expression exceeding 1.2 fold" (Ans. 6; *see also id.* at 9). For the foregoing reasons, we are not persuaded by Appellant's contention that "Barger does not disclose 'wherein a change in the second gene expression profile of at least 1.2 fold indicates that the agent or regimen is likely to be useful in retarding heart aging when administered to an individual" (App. Br. 17; *see* Reply Br. 8).

## **CONCLUSION OF LAW**

The preponderance of evidence on this record supports Examiner's finding that Barger teaches Appellant's claimed invention. The rejection of claim 15 under 35 U.S.C. § 102(b) as being anticipated by Barger is affirmed. Claims 16–20 are not separately argued and fall with claim 15.

Non-Statutory Subject Matter:

### **ISSUE**

Does the evidence of record support Examiner's finding that Appellant's claimed invention is directed to non-statutory subject matter?

#### **ANALYSIS**

Examiner concludes that Appellant's claim 15 "is directed to non-statutory subject matter" (Ans. 2–4). We adopt Examiner's findings concerning the scope and content of the prior art (*id.*).

Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 134 S. Ct. 2347, 2355 (2014) sets forth the following two-step analysis for determining patent eligibility under Section 101:

First, we determine whether the claims at issue are directed to one of those patent-ineligible concepts [e.g., a law of nature, natural phenomenon, or abstract idea]. If so, we then ask, what else is there in the claims before us? . . . We have described step two of this analysis as a search for an inventive concept—i.e., an element or combination of elements that is sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the ineligible concept itself.

*Id.* (alterations, citations, and quotation marks omitted).

Examiner finds, *inter alia*, that Appellant's claim 15 "is drawn to a process that utilizes a natural correlation for predictive purposes, i.e. to determine if a treatment will be effective in retarding heart aging" (Ans. 3). In this regard, we agree with Examiner's finding that the "step of comparing expression profiles is a mental step that invokes [a] natural principle" (Ans. 3–4).

We also agree with Examiner's findings that the remaining method steps of Appellant's claim 15

are performed to determine a gene expression profile, those of *isolating* nucleic acids from heart tissue, *hybridizing* the nucleic acids to a plurality of probes and *detecting* the hybridization complexes. However, as evidenced by Barger . . . these steps are considered routine and conventional within the art. Thus,

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they are not sufficiently specific to impose a meaningful limit on the scope of [] claim [15].

(Ans. 3; *see* Reply Br. 7 ("Appellants agree that general[ly] hybridization and detecting using probes is well-known in the art").)

[S]uccinctly [stated,] the claims inform a relevant audience about certain laws of nature; any additional steps consist of well-understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately. For these reasons we believe that the steps are not sufficient to transform unpatentable natural correlations into patentable applications of those regularities.

Mayo Collaborative Services v. Prometheus Laboratories, Inc., 132 S. Ct. 1289, 1298 (2012).

For the foregoing reasons, we are not persuaded by Appellant's contentions to the contrary (App. Br. 13–16; Reply Br. 5–7). In this regard, we note, as discussed above, that Appellant's "claim 15 does not [require] that the first gene expression profile is 'based on Ctnnb1' or that a change in the second gene expression profile is 'based on genes related to Wnt signaling" (Ans. 8–9). Therefore, we are not persuaded by Appellant's intimation that the claimed invention involves a gene expression profile based on Ctnnb1 or genes related to Wnt signaling (Reply Br. 6–7).

### **CONCLUSION OF LAW**

The evidence of record supports Examiner's finding that Appellant's claimed invention is directed to non-statutory subject matter. The rejection of claim 15 under 35 U.S.C. § 101 as directed to non-statutory subject matter is affirmed. Claims 16–20 are not separately argued and fall with claim 15.

# TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

# <u>AFFIRMED</u>